UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: 07-JAN-2003

Subject: Imidacloprid. Section 3 Request for Use on Mustard Seed Following Seed Treatment. Summary of Analytical Chemistry and Residue Data.

DP Barcode:	D286730	Case No:	295237
PC Code:	129099	Submission:	S624917
40 CFR	§180.472	PP#:	2E06458

From: Jennifer R. Tyler, Chemist
Registration Action Branch 1 (RAB1)
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Through: G. Jeffrey Herndon, Branch Senior Scientist
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To: Robert Forrest/Shaja Brothers, PM Team 05
Registration Division (RD) (7505C)

The Interregional Research Project No. 4 (IR-4), on behalf of the Agricultural Experiment Station of Idaho (ID), has submitted a petition for the establishment of a permanent tolerance for the combined residues of imidacloprid (1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, all expressed as 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine, in/on mustard seed at 0.05 ppm.

No crop-specific data were submitted in conjunction with this petition. IR-4 has proposed that HED translate previously submitted residue data for canola (PP# 5F4534) to mustard seed.

Executive Summary

Provided a revised Section F is submitted to include the correct chemical name for the active ingredient (ai), HED concludes that there are no residue chemistry data requirements that would preclude the establishment of a tolerance for residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, in/on mustard, seed at 0.05 ppm. A human-health risk assessment will be prepared as a separate document.

Residue Chemistry Deficiencies

- Revised Section F.

Background

Imidacloprid is an insecticide registered for uses on a variety of crops for the control of aphids, cucumber beetles and whiteflies (including Sweet potato or Silverleaf whitefly). Imidacloprid is a member of the pyridylmethylamine class of compounds. Its mode of action is the disruption of the nervous system by acting as an inhibitor at nicotinic acetylcholine receptors. Imidacloprid blocks the signals that are induced by acetylcholine at the post-synaptic membrane, resulting in normal nerve function impairment.

Tolerances are currently established for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, under 40 CFR §180.472 in/on various plant and livestock commodities. Section 18 Emergency Exemption tolerances with expiration/revocation dates are established in/on plant commodities under 40 CFR §180.472(b), and indirect or inadvertent tolerances are established as a result of application of the pesticide to growing crops and other non-food crops under 40 CFR §180.472(d).

In a memo dated 2/2/99, HED recommended for the establishment of a permanent tolerance for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as imidacloprid in/on canola seed at 0.05 ppm (Memo, Y. Donovan, D251449).

As mentioned previously, no crop-specific data were submitted in conjunction with this petition. IR-4 has proposed that HED translate previously submitted residue data for canola (PP# 5F4534) to mustard seed. On 3/28/01, the HED Scientific Advisory Council (ChemSAC) determined that canola seed treatment field trial data may be translated to mustard seed provided that residues in the harvested seed are nonquantifiable (ChemSAC Minutes; 5/17/01). In addition, since this decision, ChemSAC agreed to establish Oilseed Crop Group 20. The representative commodities for the crop group are rapeseed (canola varieties only) and sunflower, seed. Members of this Crop Group will be rapeseed, seed; Indian rapeseed; Indian mustard, seed: field mustard, seed; black mustard, seed; flax, seed; sunflower, seed; safflower, seed; and crambe, seed ("Reviewer's Guide...", B. Schneider, 14-JUN-2002). Canola is the representative crop that covers several oilseeds, including mustard seed.

860.1200 Directions for Use

The petitioner is proposing use of imidacloprid on mustard seed as a seed treatment to control aphids, flea beetles and wireworms. Specimen labels were provided for Gaucho® 600 Flowable (EPA Reg. No. 7501-173), a liquid formulation containing 5 lb ai/gal; and Gaucho® 480 Flowable (EPA Reg. No. 7501-155), a liquid formulation containing 4 lb ai/gal. The maximum application rate for both formulations may not exceed 1 lb. ai/hundredweight (cwt) of seed (25.6 fl. oz. of Gaucho® 600/cwt or 32 fl. oz. of Gaucho® 480/cwt).

Both formulations are proposed for one time application to mustard seed as a commercial seed treatment or as an end-use seed treatment on agricultural establishments at, or immediately before, planting. The products are to be used in liquid or slurry treaters. If the entire container is not used at one time, the liquid containing the product must be mixed thoroughly before use. All tank mixes must be pre-tested to determine physical compatibility between formulations. No pre-harvest interval (PHI) is specified, but for seed treatments PHIs are "built-in" by the time required for the plants to reach harvestable stages of growth. The purchaser of Gaucho® is responsible for ensuring that all seed treated with it is adequately dyed with a suitable color to prevent its accidental use as food for man or feed for livestock. Table 1 is a comparison of the registered uses of imidacloprid on canola with the proposed uses on mustard seed.

Table 1. Summary of Directions for Registered and Proposed Uses of Imidacloprid

Applic. Type	RTI [1] (days)	Formulation (EPA Reg. No.)	Applic. Rate (lb ai/cwt)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI [2] (days)	Use Directions and Limitations
Canola							
Seed-treatment	NA [3]	Gaucho® 480 F (EPA Reg No. 7501-155)	0.5-1.0	1	1.0	NA	Treated seeds are not to be used for or mixed with food or livestock feed, or processed for oil.
Seed-treatment	NA	Gaucho® ST (EPA Reg No. 7501-159)	0.5-1.0	1	1.0	NA	Imidacloprid treated canola seed must be properly labeled and easily identified as treated seeds.
Mustard Seed							
Seed-treatment	NA	Gaucho® 480 F (EPA Reg No. 7501-155)	0.5-1.0	1	1.0	NA	Treated seeds are not to be used for or mixed with food or livestock feed, or processed for oil.
Seed-treatment	NA	Gaucho® 600 F (EPA Reg No. 7501-173)	0.5-1.0	1	1.0	NA	Imidacloprid treated mustard seed must be properly labeled and easily identified as treated seeds.

[1] RTI = Retreatment Interval.
[2] PHI = Preharvest Interval.
[3] NA = Not Applicable.

HED concludes that the proposed use directions are adequate and are supported by the previously submitted residue data on canola (PP#5F4534).

860.1300 Nature of the Residue - Plants and Livestock

Data concerning the metabolism of imidacloprid in apples, potatoes, tomatoes, eggplant, cottonseed, field corn, tobacco, ruminants, and poultry have been submitted and reviewed in conjunction with PP#3F4169/3H5655 (Memos, F. Griffith, 9/20/93, D185148; 6/8/94, D200233; and 2/29/96, D217632). The results of the aforementioned plant and livestock metabolism studies were presented to the HED Metabolism Committee on 6/22/93 (Memo, F. Griffith, 6/18/93; No Barcode). The nature of imidacloprid residues in plants and livestock is adequately

understood. The residue of concern in plants and livestock is imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, as specified in 40 CFR §180.472.

860.1340 Residue Analytical Methods

Adequate enforcement methods are available for determination of imidacloprid residues of concern in plants (Bayer Gas Chromatography/Mass Spectrometry (GC/MS) Method 00200) and livestock commodities (Bayer GC/MS Method 00191). These methods have undergone successful EPA petition method validations (PMVs), and the registrant has fulfilled the remaining requirements for additional raw data, method validation, independent method validation (ILV), and an acceptable confirmatory method (Memos, F. Griffith, 6/18/93, D187911; 6/1/94, D202113; 6/8/94, D200233; 6/8/95, D213252; and 12/18/95; D221591).

This method has been adequately validated on a variety of crops, including field corn (Memo, Y. Donovan, 7/12/00; D224074); and, therefore, is adequate for determining residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, in/on mustard seed.

860.1360 Multiresidue Method (MRM)

Bayer Corporation previously submitted adequate MRM recovery data for imidacloprid and the metabolites guanidine imidacloprid (WAK 4140), olefin imidacloprid (WAK 3745), hydroxy imidacloprid (WAK 4103), and 6-chloronicotinic acid (6-CNA) through Food and Drug Administration (FDA) Protocols A through E (Memos, F. Griffith, 6/18/93, D187911; 7/15/93, D193027; 6/8/94, D200233; and 6/22/94, D194206). Imidacloprid and its metabolites were not recoverable by these methods. The results of the MRM testing for imidacloprid were forwarded to FDA for inclusion in the Pesticide Analytical Method Volume I (PAM I) (Memo, F. Griffith 7/15/93, D193005).

860.1380 Storage Stability

No storage stability data were submitted in conjunction with the current petition. The previously submitted storage stability data indicate that residues of imidacloprid and its metabolites are relatively stable under frozen storage conditions in/on fortified samples of field corn forage, grain and fodder for up to 24 months. The submitted storage stability data are adequate to support the proposed use on mustard seed.

860.1480 Meat, Milk, Poultry, and Eggs

There are no livestock feed commodities associated with the proposed use on mustard seed. However, acceptable ruminant and poultry feeding studies have been submitted and reviewed with PP# 3F4169/3H5655 (Memos, F. Griffith, 9/20/93, D185148; and 6/8/94, D200233).

860.1500 Crop Field Trials

No mustard seed field trial data were submitted in support of the petition. Adequate canola residue data have been submitted by the petitioner and reviewed by HED in conjunction with PP#5F4534 (Memos, F. Griffith, 9/25/95, D216234; and Y. Donovan, 7/12/00, D224074). No total imidacloprid residues were detected in any of the control canola seed to the LD of <0.01 ppm. Total imidacloprid residues on mature canola seed ranged from 0.005 to 0.04 ppm with only 1 sample at < 0.005 ppm and all samples averaging 0.015 $\pm$ 0.012 ppm, n = 12.

The available field trial data for canola will support the proposed tolerances for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent, in/on mustard, seed at 0.05 ppm. HED notes that in Section F of the subject petition, the chemical name for the ai is presented incorrectly as "1-[(6-chloro-3-pyridinyl)methyl]-*N*-2-imidazolidinimine." A revised Section F should be submitted to include the correct chemical name for imidacloprid "1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine."

860.1520 Processed Food and Feed

No mustard seed processing data were submitted in support of the petition. According to the current guidance, data on processed food and feed are not required for uses of pesticides on mustard seed.

860.1850/1900 Confined/Field Accumulation in Rotational Crops

No rotational crop data were submitted in conjunction with this petition. According to the current guidance, mustard seed is a rotated crop. The following rotational crop restrictions are currently on the Gaucho® 480 F and Gaucho® 600 F labels:

Commodity	PBI
Barley; Broccoli; Broccoli, Chinese; Broccoli raab; Brussels Sprouts; Cabbage, Chinese mustard; Cabbage, Chinese; Cabbage; Canola; Cauliflower; Collards; Cotton; Cucurbits; Eggplant; Ground Cherry; Kale; Kohlrabi; Lettuce; Mustard Greens; Pepinos; Pepper; Potatoes; Rape greens; Sorghum; Sugarbeets; Tomatillo; Tomato; Wheat	Immediate Plantback
Cereals (including buckwheat, corn, millet, oats, popcorn, rice, rye, and triticale); Legume (including soybeans, beans and peas); Safflower	30-day
All Other Crops	12-month

No mustard seed confined rotational crop data were submitted in support of the petition. Adequate canola confined rotational crop data have been submitted by the petitioner and reviewed by HED in conjunction with PP#5F4534 (Memo, F. Griffith, 9/25/95, D216234). Canola can be rotated immediately following the harvest of crops treated with imidacloprid. Therefore, mustard seed can be rotated immediately following the harvest of crops treated with

imidacloprid. If the petitioner chooses, the label can be revised to include mustard seed in the list of commodities with no plantback restriction.

860.1550 Proposed Tolerances

Provided a Revised Section F is submitted, the residue chemistry database supports the establishment of the permanent tolerances for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, in/on the RACs listed in Table 2.

Table 2. Tolerance Summary for Imidacloprid

Commodity	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Comments (correct commodity definition)
mustard, seed	0.05	0.05	

The International Residue Limit Status (IRLS) Sheet is attached as Attachment 1. There are no established Codex, or Mexican maximum residue limits (MRLs) for imidacloprid in/on mustard seed. There is currently the a Canadian MRL of 0.05 ppm for residues of imidacloprid and metabolites containing the 6-chloropicolyl moiety on mustard seed. The Canadian tolerance expression and MRL are equivalent to the US tolerance expression and recommended tolerance level. Therefore, harmonization is not an issue at this time.

cc: J. Tyler (RAB1)
RDI: G. Herndon (12/19/02), RAB1 Chemists (12/19/02)
J. Tyler: 809B: CM#2: (703)305-5564: 7509C: RAB1

ATTACHMENT 1

INTERNATIONAL RESIDUE LIMIT STATUS

Chemical Name: **1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine**	Common Name: **Imidacloprid**	**x Proposed tolerance** □ Reevaluated tolerance □ Other	Date: **12/30/02**

Codex Status (Maximum Residue Limits)	U. S. Tolerances
X No Codex proposal step 6 or above □ No Codex proposal step 6 or above for the crops requested	Petition Number: **2E6458** DP Barcode: **D286730** Other Identifier:
Residue definition (step 8/CXL):N/A	Reviewer/Branch: **J. Tyler/RAB1**
	Residue definition: **Imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent**

Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
		Mustard Seed	0.05

Limits for Canada	Limits for Mexico
□ No Limits □ No Limits for the crops requested	□ No Limits X No Limits for the crops requested
Residue definition:Parent and metabolites containing the 6-chloropicolyl moiety.	Residue definition: imidacloprid

Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)
mustard seed	0.05		

Notes/Special Instructions:S. Funk, 01/06/03.

Rev. 1998

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R058479

Chemical:	**Imidacloprid**
PC Code:	**129099**
HED File Code	**11000 Chemistry Reviews**
Memo Date:	**01/07/2003 12:00:00 AM**
File ID:	**DPD286730**
Accession Number:	**412-04-0047**

HED Records Reference Center
04/05/2004